

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE: FOSAMAX PRODUCTS LIABILITY :	MDL No. 1789
LITIGATION :	
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<u>This Document Relates to</u> :	<u>1:06-cv-7631 (JFK)</u>
:	
<u>Bessie Flemings v. Merck &amp; Co., Inc.</u> :	
<u>1:06-cv-7631(JFK)</u> :	<u>OPINION &amp; ORDER</u>
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APPEARANCES:

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**JOHN F. KEENAN, United States District Judge:**

Before the Court is defendant Merck Sharp & Dohme Corp.'s ("Merck") motion for summary judgment against plaintiff Bessie Flemings ("Flemings" or "Plaintiff"). This case has been selected for the second of three bellwether trials in a multi-district products liability litigation concerning the

osteoporosis drug Fosamax. For the reasons set forth below, the motion is granted.

### **I. BACKGROUND**

The following facts are taken from the parties' Local Rule 56.1 Statements and the exhibits attached thereto. Unless otherwise noted, the facts are undisputed.

#### **A. Fosamax<sup>1</sup>**

Fosamax is an oral bisphosphonate manufactured by Merck for the treatment of osteoporosis. Plaintiff and her experts contend that Merck has long known of studies and reports linking bisphosphonate use with the development of osteonecrosis of the jaw ("ONJ"). Merck did not warn consumers regarding a link between Fosamax and ONJ until July 2005, when it made the following FDA-approved addition to Fosamax's label:

Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking bisphosphonates. Most reported cases of bisphosphonate-associated osteonecrosis have been in cancer patients treated with intravenous bisphosphonates, but some have occurred in patients with postmenopausal osteoporosis.

(Def's Ex. 15.)

#### **B. Bessie Flemings**

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<sup>1</sup> The Court provides information regarding Fosamax only to the extent that it is relevant to the instant motion. For further information on the drug, see the Court's ruling on the parties' Daubert motions, In re Fosamax Prods. Liab. Litig., No. 06 MD 1789, 2009 WL 2222910 (S.D.N.Y. July 27, 2009).

Plaintiff Bessie Flemings is a 74-year old Mississippi resident who alleges that she developed ONJ in 2006 as a result of taking Fosamax.

Flemings has a history of serious medical problems. Flemings has been smoking cigarettes since she was eight years old. She has long suffered from severe chronic obstructive pulmonary disease ("COPD") and continues to smoke cigarettes even though she is now dependent on an oxygen tank. Among other health problems, she has congestive heart failure, peripheral vascular disease, and she developed skin cancer on the outside of her mouth.

Flemings was diagnosed with severe osteoporosis in December 1997. That month, her family physician, Dr. Walter Rose ("Dr. Rose"), prescribed Fosamax to treat her osteoporosis. Flemings has fallen several times since she was diagnosed with osteoporosis, fracturing her knee and injuring her back on two such occasions.

From 2004 to the present, Flemings's primary dentist has been Dr. David McDaniel ("Dr. McDaniel"). Dr. McDaniel has described Plaintiff's oral hygiene as "poor." Flemings has lost many of her teeth and does not regularly have her teeth cleaned. On April 19, 2006, Flemings visited a different dentist, Dr. Jeff Andrews ("Dr. Andrews"). According to the records from that visit, Dr. Andrews found a bone sliver in the lower left

side of Plaintiff's mouth and an "ulcer on the side of her tongue due to trauma." (Def.'s Ex. 12.). Dr. Andrews removed the bone sliver and a root tip.

On April 27, 2006, Flemings visited Dr. McDaniel. He found exposed bone extruding through the tissue in the lower left side of Flemings's mouth. He was not aware that Flemings had visited Dr. Andrews earlier that month. According to Dr. McDaniel, the exposed bone was the size of a dime and appeared necrotic. Dr. McDaniel did not know how to treat the condition, so he phoned Flemings's regular physician, Dr. Rose, and Dr. Nichols, a maxillofacial surgeon. Dr. McDaniel instructed Flemings to discontinue use of Fosamax for two weeks.

Exactly two months later, on June 27, 2006, Flemings again visited Dr. McDaniel. According to McDaniel, the area of exposed bone appeared to be healing and had decreased in size. He instructed Flemings to return one week later. She did not return to visit Dr. McDaniel for another two years. No exposed bone was noted at that time. Her condition, to the best of Dr. McDaniel's and Dr. Rose's knowledge, healed completely.

### **C. Testimony of Flemings's Doctors**

In opposing this motion for summary judgment, Plaintiff points to the medical records of Dr. Rose as evidence that Plaintiff's injury was caused by Fosamax. One of Dr. Rose's records relating to his treatment of Flemings, dated May 1,

2006, states in part: "Has a destructive process of her left mandible. She saw Dr. McDaniel. He thought it was related to Fosamax." (Pl.'s Ex. 23). A separate record, dated May 30, 2006, states: "Her CAT scan showed no problems with her left jaw. . . . We have switched her from Fosamax over to Miacalcin nose spray. I think her drug reaction was to Fosamax." (Id.)

Dr. Rose and Dr. McDaniel were both deposed in this matter. At his deposition, Dr. McDaniel could not give an opinion as to what caused the injury to Flemings's jaw. He stated:

Q. All right. Did you arrive at any conclusion as to what caused that condition at that time?

A. No.

. . . .

Q. Now, did you ever have a discussion with Ms. Flemings about whether Fosamax caused her condition?

A. Yes.

Q. And what did -- tell us what you can recall about that discussion.

A. I recall that -- of what I had read about the bisphosphonate, that it was in Fosamax. The studies that -- at the time when I saw her the first time, most of the studies were on IV chemotherapy and drugs that had bisphosphonate. But I did know that Fosamax had bisphosphonate in it.

Q. Okay. And did you -- did she ask you whether that's what caused her problem?

A. I don't recall exactly like that.

Q. All right. And did you tell her that that was what caused her problem?

A. No.

Q. To this day, Dr. McDaniel, do you have an opinion as to whether that's what caused her problem?

A. No.

(Pl.'s Ex. 21 at 29:17 - 34:18.) The pertinent portions of Dr. Rose's testimony regarding the cause of Plaintiff's condition are as follows:

Q. Did you play any part in treating whatever the problem was in her jaw at the time?

A. I think we treated it with antibiotics and we stopped her Fosamax at that time and tried -- switched over to Miacalcin.

Q. At that point in time did -- had you done any reading about an association between bisphosphonate drugs and osteonecrosis?

A. [W]e were beginning to get some talk among us and dentists and so forth about this report of osteonecrosis, as they were calling it. We called it an aseptic or avascular necrosis where we -- in other parts of the body, but I think they were calling it osteonecrosis that possibly was related to IV Fosamax. And so I mean, the -- there was beginning to be a little hum in the medical and dental community about that. And so that's when we thought that maybe this was one of those cases.

. . . .

Q. And do you have an opinion today as to whether Fosamax was a cause or contributing factor of the problem she had in her jaw?

A. What little I know about it -- and it's very little -- I think it probably may have been a contributing factor in her teeth. But her -- she had such generalized osteoporosis, I'm not -- I can't be -

- I can't 100 percent say that it was. My understanding of how osteonecrosis works is that if it is due to osteonecrosis and you stop the drug, that it will heal up, because it's not like the true avascular necrosis that we see in bones and other places in the body. And that if you stop the Fosamax, or the Actonel or whatever it is that you may have a question about, the area will heal up. And so that to me, it could have healed up, I guess, either from stopping the Fosamax or it could have healed up on its own if it was just an - just a horrible-looking abscess. I'm sure I haven't answered that correctly, but that's my understanding of osteonecrosis.

Q. I have no idea how much reading you've done on the subject or what -- where you obtained your information, but do you know whether there's any medical literature to support a conclusion that stopping the drug will aid in the healing process?

A. No, sir. And I haven't read, now. I haven't read or researched anything like this.

. . . . .

Q. I just want to make sure that I understand your testimony. Is it an accurate summary that you -- your testimony is that you don't know whether Fosamax either caused or contributed to the lesion that she had in her jaw back in April of 2006.

[Plaintiff's counsel]: Object to the form.

A. I can't say. That was the reason that I called -- told the Merck rep when she came around, and told them, you know, and we filed a report with Merck right away that we thought that we had a possible case of Fosamax osteonecrosis. But I didn't -- I mean, I'm not a dentist. I'm not an oral surgeon. And so I could not say that. My understanding, though, still -- and I don't know whether I got that from a course or whether I got that out of some reading or something -- that if it -- if Fosamax is or the bisphosphonates is the culprit, that if you stop it the area will heal.

(Pl.'s Ex. 20 at 45:16 - 51:6.)

## II. DISCUSSION

The parties agree that Mississippi law applies, as the action originally was filed in the United States District Court for the Northern District of Mississippi, which is also the Plaintiff's home state. (Def. Mem. at 7; Pl. Opp'n at 2); Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941) (holding that a federal diversity court applies the choice of law rules of the state in which it sits). It follows, therefore, that the Mississippi Product Liability Act (the "MPLA") governs this matter. See Miss. Code Ann. § 11-1-63; cf. Guy v. Crown Equip. Corp., 394 F.3d 320, 324 (5th Cir. 2004) (holding that the substantive provisions of the MPLA apply to all products liability actions filed after July 1, 1994). Under the MPLA, Plaintiff must prove "by the preponderance of the evidence that at the time the product left the control of the manufacturer or seller": (1) the product contained a manufacturing defect; (2) the product did not contain adequate warnings or instructions; (3) the product was designed in a defective manner; or (4) the product breached an express warranty. Miss. Code Ann. § 11-1-63(a).

Plaintiff asserts claims under the first three provisions of the MPLA. Plaintiff also asserts a cause of action under the theory of negligence per se because the Fosamax label did not comply with FDA regulations on drug label warnings.



Merck asks the Court to grant summary judgment on the following grounds:

- 1) Plaintiff cannot show causation.
- 2) Plaintiff's claims fail as a matter of law under the Mississippi Product Liability Act.
- 3) Plaintiff's request for punitive damages does not meet the applicable standard.

In its opposition to the motion for summary judgment, Plaintiff does not contest Merck's motion to the extent it seeks dismissal of Plaintiff's claims of (1) design defect; (2) manufacturing defect; or (3) negligence per se. As such, those three causes of action are dismissed. Plaintiff's sole remaining cause of action is the failure to warn claim.

#### **A. Standard of Review**

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The moving party bears the burden of demonstrating that summary judgment is appropriate. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). "[I]t ordinarily is sufficient for the movant to point to a lack of evidence to go

to the trier of fact on an essential element of the nonmovant's claim." Cordiano v. Metacon Gun Club, Inc., 575 F.3d 199, 204 (2d Cir. 2009). Where the moving party meets that burden, the opposing party must come forward with specific admissible evidence demonstrating the existence of a genuine dispute of material fact. Celotex, 477 U.S. at 322-23.

### **B. Causation**

Plaintiff brought her claim for failure to warn under both the strict liability and negligence counts of her Complaint. "Although a plaintiff in a prescription drug liability case may alternatively rely on strict liability and negligence principles, these principles merge into one inquiry; the adequacy of the defendant's warnings." Bennett v. Madakasira, 821 So.2d 794, 804 (Miss. 2002). To prevail on a failure to warn claim, "Mississippi law requires a plaintiff to establish that an adequate warning would have prevented the plaintiff's injury." Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 811 (5th Cir. 1992). To satisfy the causation element, plaintiff must establish, by a preponderance of the evidence, both: "(1) that an adequate warning would have prevented the treating physician from administering the drug;<sup>2</sup> and (2) that the injury would not

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<sup>2</sup> To satisfy this element, "a plaintiff may introduce either objective evidence of how a reasonable physician would have responded to an adequate warning, or subjective evidence to establish how the treating physician would have responded." Bennett, 821 So.2d at 807.

have occurred had the drug not been administered." Id.; Bennett, 821 So. 2d at 807.

Merck claims that Plaintiff has established neither. With regard to the element of establishing that the Plaintiff would not have developed an injury but for her use of Fosamax (i.e., specific causation), Plaintiff has presented (1) expert testimony to establish that Fosamax generally can cause ONJ and (2) the deposition testimony of her treating physicians. Merck contends that Dr. Rose and Dr. McDaniel did not provide an opinion regarding the cause of her injury, but merely speculated as to the possible effect of the Fosamax ingested by the Plaintiff. Merck argues that even if their testimony can be construed as opinions, their testimony is inadmissible under Rule 702 of the Federal Rules of Evidence and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592 (1993), and thus Plaintiff cannot establish her failure to warn claim as a matter of law.<sup>3</sup>

Merck argues that Plaintiff's claim is insufficient as a matter of law because Plaintiff has presented no evidence that a different warning would have prevented Dr. Rose from prescribing

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<sup>3</sup> Plaintiff argues that, by not raising this argument in its Daubert motion, Merck waived its challenge to the expert opinions of Plaintiff's treating physicians on the specific cause of her injury. However, in its Daubert motion, Merck expressly challenged the admissibility of their opinions, stating that it would rely on the arguments made in the instant motion. (Def.'s Mem. of Law in Supp. of Motion to Exclude Expert Testimony on Daubert Grounds at 72.) The Court therefore does not consider Merck's challenges waived.

her Fosamax. Plaintiff provides evidence that purportedly establishes that Dr. Rose may not have prescribed Plaintiff Fosamax had he known of Fosamax's true benefits. Merck contends that it does not matter what Dr. Rose would have done had he known of the true benefits; all that is relevant here is whether the failure to warn of the drug's true risks proximately caused Plaintiff's injury.

### **1. Admissibility of Evidence on Specific Causation**

Rule 702 specifies that a witness may be qualified as an expert "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Qualification as an expert is viewed liberally and may be based on "a broad range of knowledge, skills, and training." In re TMI Litig., 193 F.3d 613, 664 (3d Cir. 1999); In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig., No 1-00-1898, 2008 WL 1971538, at \*5 (S.D.N.Y. May 7, 2008) (stating that "[c]ourts within the Second Circuit have liberally construed expert qualification requirements" (internal quotation marks omitted)). However, the expert must have relevant experience and qualifications such that whatever opinion he will ultimately express would not be speculative. See Quintilla v. Komori Am. Corp., No. 04 Civ. 5227, 2007 WL 1309539 (E.D.N.Y. May 4, 2007); Barban v. Rheem Textile Sys., Inc., No. 01 Civ. 8475, 2005 WL 387660 (E.D.N.Y. Feb. 11, 2005).

Not only must the witness qualify as an expert, but his testimony must be scientifically valid. The Daubert Court interpreted Rule 702 to require district courts to act as gatekeepers by ensuring that expert scientific testimony "both rests on a reliable foundation and is relevant to the task at hand." Daubert, 509 U.S. at 597. This requires "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 592-93. Daubert set forth a non-exclusive list of factors that courts might consider in gauging the scientific validity of proffered testimony. Id. at 593-95. These factors are: (1) whether the theory has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error and whether standards and controls exist and have been maintained with respect to the technique; and (4) the general acceptance of the methodology in the scientific community. Id.

**a. Dr. McDaniel**

Plaintiff cannot establish specific causation through the opinion of Dr. McDaniel because, in short, he does not have an opinion. He testified at his deposition that he never formed an opinion as to what caused Plaintiff's injury. (Pl.'s Ex. 21 at 29:17 - 34:18.) The evidence cited by Plaintiff which

purportedly shows that he thought her injury was caused by Fosamax is a note within Dr. Rose's records which states as much. Even assuming arguendo that Dr. McDaniel is qualified as an expert to diagnose bisphosphonate-associated ONJ, the statement attributed to Dr. McDaniel within Dr. Rose's medical records is inadmissible for the truth of the matter asserted. See Walter v. Kubicz, 996 F. Supp. 336, 340 (S.D.N.Y. 1998). As such, Plaintiff cannot defeat summary judgment with the testimony of Dr. McDaniel.

**b. Dr. Rose**

Initially, the Court must determine whether Dr. Rose properly qualifies as an expert under Rule 702. Dr. Rose briefly testified at his deposition regarding his background and qualifications. Dr. Rose has been practicing medicine at the Indianola Family Practice in Indianola, Mississippi since 1965. He is board certified in family medicine, and has received awards for his missionary work in Honduras. Through his testimony, however, Dr. Rose also put into question whether he is qualified to diagnose bisphosphonate-associated ONJ. For example:

- Dr. Rose testified that he knows "very little" regarding the alleged link between Fosamax and ONJ. (Pl. Ex. 20 at 46:24 - 46:25.)
- Dr. Rose states that he has not researched the alleged link between ONJ and Fosamax. (Id. at 47:15 - 47:19.)

- He could not recall where he developed the requisite knowledge to diagnose Plaintiff's injury, but noted that there was a "little hum in the medical and dental community" (id. at 46:9 - 46:12) and suspected that he developed his theory "from a course or . . . [a] reading or something." (Id. at 51:1 - 51:10.)
- When asked whether Fosamax either caused or contributed to the lesion in Flemings's mouth, Dr. Rose responded: "I can't say. . . . I'm not a dentist. I'm not an oral surgeon. And so I could not say that." (Id. at 50:21 - 51:6.)

The Second Circuit has construed the expert qualification requirements liberally, holding that a doctor need not be a specialist in the exact area of medicine implicated by the plaintiff's injury. McCulloch v. H.B. Fuller Co., 61 F.3d 1038, 1043 (2d Cir. 1995) (rejecting the argument that the expert "had to be a specialist in environmental medicine to provide expert testimony" regarding an injury allegedly caused by glue fumes as "an unwarranted expansion of the gatekeeper role announced in Daubert"). Although the qualification requirement is liberally construed, "it is not a nullity." Mancuso v. Consol. Edison Co. of N.Y., Inc., 967 F. Supp. 1437, 1442 (S.D.N.Y. 1997); see also Prohaska v. Sofamor, S.N.C., 138 F. Supp. 2d 422, 437 (W.D.N.Y. 2001) (finding a medical doctor unqualified to render an expert opinion on causation "[b]ecause of his dearth of knowledge" in the relevant topics at issue). While Dr. Rose need not be an oral surgeon or a specialist in oral pathology to qualify as an expert in this matter, he must have "some specialized knowledge

. . . as a result of training or experience."<sup>4</sup> Mancuso, 967 F. Supp. at 1443; see also Fed. R. Civ. P. 702; McCulloch, 61 F.3d at 1043.

Plaintiff has not identified any "specialized knowledge" Dr. Rose may have that qualifies him as an expert in this case; at his deposition – the transcript of which is the Court's sole source of information in the record regarding Dr. Rose's background, education, and the theories upon which he based his diagnosis of Plaintiff – Dr. Rose did little to bolster his qualifications in this area, but instead repeatedly qualified his diagnosis by admitting that "he knows little" regarding the topic and that he was "sure that [he had not] answered [the deposition questions] correctly." (Pl.'s Ex. 20 at 46:24 – 47:14.) He has not personally researched the alleged link

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<sup>4</sup> As Plaintiff's treating physician, Dr. Rose's opinion on causation "is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for purposes of litigation." Turner v. Iowa Fire Equip. Co., 229 F.3d 1202, 1207 (8th Cir. 2000); see also Amorgianos v. National R.R. Passenger Corp., 303 F.3d 256, 270 (2d Cir. 2002). Since Dr. Rose was Plaintiff's treating physician, though, we do not have the concern shared by the courts in Mancuso and Prohaska of "litigation-driven expertise," where an individual "was not in fact an expert . . . when he was hired by plaintiffs, but that he subsequently attempted, with dubious success, to qualify himself as such by a selective review of the relevant literature." Prohaska, 138 F. Supp. 2d at 437 (citing Mancuso). Although the courts in Mancuso and Prohaska excluded the testimony of a proposed expert based in part on this concept of "litigation-driven expertise," it nonetheless stands that Dr. Rose must point to some "specialized knowledge" that qualifies him to serve as an expert in this proceeding.



between Fosamax and ONJ; nor has he read the various reports and studies on the issue.

Moreover, unlike the proposed expert witness in McCulloch, Dr. Rose does not substitute his lack of formal training in this area with extensive "practical experience." It appears from Dr. Rose's deposition that he had seen only one patient other than Flemings in his professional career who he suspected had developed bisphosphonate-associated ONJ. (Pl.'s Ex. 20, at 51:12 - 51:21). He did not state his basis for the conclusion that the other patient's injury was caused by bisphosphonate, and he provided no other detail regarding the patient's condition.

Overall, the limited record shows that Dr. Rose has no qualification to serve as an expert in this matter other than his medical degree and years of practicing family medicine. The Court does not question Dr. Rose's qualifications as a practitioner of family medicine, but Dr. Rose admittedly lacks the "specialized knowledge" to provide an expert opinion as to whether Plaintiff's injury was caused by Fosamax.

Even if the Court were to find that Dr. Rose is qualified to serve as an expert in this case, the methodology he used to form his opinion similarly is unreliable. Although the methodology upon which Dr. Rose based his diagnosis was not articulated in much detail at his deposition, he appears to rely

primarily on the temporal relationship between Plaintiff discontinuing her use of Fosamax and her injury healing. Merck contends that this is merely an inadmissible post hoc ergo propter hoc (i.e., after the fact, therefore because of the fact) argument. See, e.g., In re Rezulin Prods. Liab. Litig., 369 F. Supp. 2d 398, 411 n.92 (S.D.N.Y. 2005) (referring to an expert opinion based merely on temporal sequence as the post hoc ergo propter hoc fallacy). An expert's consideration of the temporal relationship between cause and effect does not make his expert opinion per se inadmissible. Several courts "have looked favorably on medical testimony that relies heavily on a temporal relationship between an illness and a causal event." Heller v. Shaw Indus., Inc., 167 F.3d 146, 154 (3d Cir. 1999); see also Zuchowicz v. U.S., 140 F.3d 381, 385 (2d Cir. 1998). A strong temporal relationship between the injury and its alleged cause may be one of several factors considered by a medical doctor to reliably determine causation, but, standing alone, relying wholly on a temporal relationship is not sound scientific methodology that is admissible under Rule 702 and Daubert. See, e.g., Zuchowicz, 140 F.3d at 385 (admitting an expert's opinion that was based in part on a temporal relationship, but also a "differential etiology method of excluding all other possible causes"); In re Zyprexa Prod. Liab. Litig., No. 04 MD 1596, 2009 WL 1357236, at \*2 (E.D.N.Y. May 12, 2009) ("A medical expert

must adequately consider possible alternative causes of an alleged disease, avoiding speculative analysis that automatically implicates a drug in the temporal chain."); Figueroa v. Boston Scientific Corp., 254 F. Supp. 2d 361, 367 (S.D.N.Y. 2003) (admitting an expert opinion based in part on temporal proximity "[b]ecause the record shows that [the expert's] opinion is based on more than his consideration of timing"); cf. Silivanch v. Celebrity Cruises, Inc., 171 F. Supp. 2d 241, 257 (S.D.N.Y. 2001) ("A temporal relationship by itself provides no evidence of causation. But such a temporal relationship can corroborate other proof of a causal nexus . . . .").

A thorough reading of Dr. Rose's deposition transcript reveals no other reasoning for his diagnosis other than the temporal relationship and "a little hum in the medical and dental community" regarding the alleged link between bisphosphonates and ONJ. (Pl.'s Ex. 20 at 46:9 - 46:12.) At his deposition, Dr. Rose did not claim to have performed a "differential diagnosis" and made no attempt to rule out other possible causes of Plaintiff's injury. "While an expert need not rule out every potential cause in order to satisfy Daubert, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." Israel

v. Spring Indus., No. 98 CV 5106, 2006 WL 3196956, at \*5 (E.D.N.Y. Nov. 3, 2006); see also Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 202 (4th Cir. 2001) ("[I]f an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert's testimony."). It is undisputed that Flemings has smoked since childhood and has poor dental hygiene. Dr. Rose had a CAT scan performed on Flemings's jaw – which Plaintiff's counsel asserts was done to rule out cancer – but, at his deposition, Dr. Rose did not rule out or otherwise address other possible causes for the injury to Plaintiff's jaw, such as trauma or infection. In fact, he suggested a plausible alternative explanation for Flemings's injury: "[I]t could have healed up, I guess, either from stopping the Fosamax or it could have healed up on its own if it was just an -- just a horrible-looking abscess." (Pl.'s Ex. 20 at 47:9 – 47:12.)

Moreover, Plaintiff does not provide the Court any scientific literature or studies that would support Dr. Rose's theory of causation. Through the course of this multi-district litigation, other experts have opined based on scientifically valid methodologies that Fosamax can cause ONJ. However, nowhere in its opposition to Defendant's motion for summary judgment, or in the exhibits attached thereto, does Plaintiff

provide the Court information regarding Dr. Rose's theory – that a patient's ONJ would heal soon after she stopped taking Fosamax only if in fact the injury was caused by the drug.<sup>5</sup> Plaintiff does not explain: (1) whether the theory has been tested; (2) whether the theory has been subject to peer review and publication; (3) the known or potential rate of error; or (4) the general acceptance of the methodology in the scientific community. Daubert, 590 U.S. at 593-95. Without an understanding of the medical authorities upon which Dr. Rose bases his opinion, the Court is left to speculate as to its legitimacy.

It is clear that Dr. Rose's opinion is derived from a "subjective belief" rather than from scientific knowledge and methodologies. Daubert, 509 U.S. at 589-90 (interpreting "scientific knowledge" to "connote[] more than subjective belief or unsupported speculation"); In re Zyprexa, 2009 WL 1357236, at \*2 ("Subjective or intuitive guesswork, as well as testimony that is insufficiently connected to the facts of the case, are grounds for rejection of a proffered expert testimony."). This

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<sup>5</sup> The Court observed in its ruling on the parties' Daubert motions that the Plaintiffs' Steering Committee and its experts "did not defend the reliability" of a similar theory – that a "drug holiday" before dental surgery reduces the risk of developing ONJ. In re Fosamax Prods. Liab. Litig., No. 06 MD 1789, 2009 WL 222910, at \*31 (S.D.N.Y. July 27, 2009). The Court therefore granted Merck's motion to preclude testimony that "cessation of Fosamax treatment is appropriate before major dental surgery." Id.

is best evidenced by Dr. Rose's own words, who when pressed at his deposition regarding his opinion, stated that he "could not say" whether Fosamax was a cause or contributing factor of Plaintiff's injury. (Pl.'s Ex. 20, at 49:21 - 50:6.)

Dr. Rose is not qualified as an expert under Rule 702 and his opinion is inadmissible under Daubert. Plaintiff has offered no other evidence to establish that Fosamax caused her to develop ONJ, and therefore her failure to warn claim is insufficient as a matter of law.

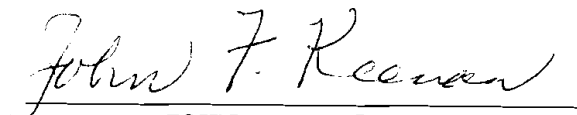
**CONCLUSION**

The Court need not address Merck's additional arguments because the lack of admissible evidence on the issue of specific causation entitles Merck to dismissal of all of Plaintiff's claims.

For the reasons stated above, Merck's motion for summary judgment is granted and this action is dismissed.

**SO ORDERED.**

**Dated:** New York, New York  
November 20, 2009

  
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**JOHN F. KEENAN**  
United States District Judge